

***Remarks***

***I. Status of the Claims***

Reconsideration of this application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 7, 30-36 and 40 are pending in the application, with claims 1, 7 and 30 being the independent claims.

Claims 37-39 have been cancelled. Claims 1, 7 and 30-33 have been amended to (a) define more particularly the viral envelope protein; (b) remove recitation of SEQ ID NOS: 5-7; and (c) to define more particularly the immunogenic properties of the claimed composition. Support for the amendments to the claims may be found in the originally-filed claims and specification, including at paragraphs [0014] and [0015]. Accordingly, these changes introduce no new matter and their entry is respectfully requested. Moreover, the removal of subject matter by amendment or cancellation is without prejudice or disclaimer thereof, and reserve the right to pursue such subject matter in subsequent application.

The Examiner has withdrawn claims 35, 36 and 40 as being drawn to nonelected species. Upon the identification of allowable subject matter in generic or linking claims, Applicants respectfully request the rejoinder and consideration of the non-elected species, in accordance with 37 C.F.R. § 1.141.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***II. Election/Restriction***

In view of Applicants' cancellation of reference to the elected species of SEQ ID NO:1, the Examiner has extended examination to SEQ ID NOs:2-4 and 9. *See* Office Action at page 2. The Examiner has not extended examination to SEQ ID NOs:5-7, asserting that these sequences do not share a sufficient sequence homology with SEQ ID NOs:2-4 and 9, citing *In re Harnisch*, 631 F.2d 1716, 206 U.S.P.Q. 300 (CCPA 1980). *See* Office Action at page 2. Applicants respectfully disagree. SEQ ID NOs:2-4 and 9 have been designed for binding to gp41/gp120 of HIV-1, while SEQ ID NOs:5-7 are designed for binding to the corresponding region(s) of gp41/gp120 from HIV-2. The divergence of SEQ ID NOs 2-4 and 9 with SEQ ID NOs:5-7 reflects underlying divergence in gp41 and gp120. However, such divergence in the sequences is not a sufficient basis to require restriction between the sequences. As each group corresponds to similar fusion-active regions on gp41/gp120, such a classification is not "repugnant to scientific classification." *Harnisch*, 631 F.2d at 1716. Accordingly, SEQ ID NOs:2-7 and 9 should all be examined together.

However, solely to advance prosecution, and not in acquiescence to the Examiner's rejection, Applicants have cancelled the subject matter which forms the basis of the present rejection. Accordingly, the rejection is overcome. Applicants reserve the right to pursue the cancelled subject matter in subsequent divisional applications, in accordance with 37 C.F.R. 1.141.

**III. Rejections Under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected claims 1 and 31 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for recitation of “or fragments thereof” in reference to viral envelope proteins. *See* Office Action at page 5, § 13. Claim 31 does not recite “or fragments thereof,” and presumably was rejected solely for dependence from claim 1. Applicants respectfully traverse the rejection. However, solely to advance prosecution and not in acquiescence to the rejections, Applicants have amended claim 1 to remove recitation of “or fragments thereof,” according to the Examiner’s suggestion. Applicants respectfully believe that the present rejection has been accommodated, and request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, second paragraph.

**IV. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description**

The Examiner has rejected claims 1-8 and 30 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action at pages 6-7, § 16. The Examiner argues that claims 1-8 and 30 lack sufficient written description support for “fragments thereof” of the recited sequences. Applicants respectfully disagree.

The written description requirement of 35 U.S.C. § 112, first paragraph, is met if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an [applicant] had possession of the concept of what is claimed. *Id.* That is “[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the

claims is not explicitly described in the specification.” *In re Alton*, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996). An applicant is not required to disclose or provide a working example of every species of a given genus in order to meet the written description requirement of 35 U.S.C. § 112 (*see Parks* and *Alton*), and subject matter that “might fairly be deduced from the original application” is considered to be described in the application as filed. *Acme Highway Products Corp. v. D.S. Brown Co.*, 431 F.2d 1074, 1080 (6<sup>th</sup> Cir. 1970) (citations omitted), *cert. denied*, 401 U.S. 956 (1971), *followed by Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981). Moreover:

[a] description of a genus of [nucleic acid molecules] may be achieved by means of a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus . . . .

*Regents of Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997).

The present specification recites the sequences of SEQ ID NOs: 1-9. Tables 1 and 2 recite carboxy- and amino-terminal deletions of SEQ ID NO:1. *See* Specification at pages 34-37. SEQ ID NO:2 is a homolog of SEQ ID NO:1. A person of ordinary skill in the art, by replacing those amino acids differing between SEQ ID NO:1 and SEQ ID NO:2, and with the aid of Tables 1 and 2, would be able to list all species of N- and C-terminal deletions of SEQ ID NO:2 and, therefore, would be able to recognize that applicants were in possession of the claimed invention as of the filing date. Similarly, those of ordinary skill in the art would recognize that applicants were in possession of all fragments of SEQ ID NOs:3,4 and 9 as of the filing date.

Moreover, *even if* Tables 1 and 2 were not provided, the application’s disclosure coupled with the knowledge of one of ordinary skill in the art provides sufficient description for one of ordinary skill in the art to be able to list all species of N- and C-

terminal deletions of SEQ ID NOs:2, 3, 4 and 9, thereby demonstrating applicants' possession of the invention at the time of filing.

Accordingly, the Examiner's rejection is overcome and Applicants respectfully request reconsideration and withdrawal of the present written description rejection under 35 U.S.C. § 112, first paragraph.

**V. Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement**

The Examiner has rejected claims 1, 7 and 30-34 under 35 U.S.C. § 112, first paragraph, asserting that the specification:

while being enabling for the claimed compositions wherein the envelope protein is an human immunodeficiency virus (HIV) gp41/gp120 complex, does not reasonably provide enablement for the claimed compositions wherein the envelope protein is any gp41/gp120 complex.

Office Action at page 7. Applicants respectfully disagree. However, solely to advance prosecution, and not in acquiescence to the rejection, Applicants have amended claims 1, 7 and 30-34 to recite that the gp41/gp120 complex is an HIV gp41/gp120 complex. As this amendment is within the scope of that which the Examiner considers enabled by the specification, Applicants respectfully assert that the rejection is overcome. Reconsideration and withdrawal of the rejection of claims 1, 7 and 30-34 under 35 U.S.C. § 112 is respectfully requested.

**VI. Rejections Under 35 U.S.C. § 103**

The Examiner has rejected claims 1 and 31 under 35 U.S.C. § 103 over Furata *et al.* (Nat. Struct. Biol. 5:276-279, hereinafter "Furata") in view of Wild *et al.* (WO

94/02505, hereinafter “Wild”). *See* Office Action at pages 11-12, § 25. The Examiner has also rejected claims 1, 7 and 30-34 under 35 U.S.C. § 103 over Furata in view of Wild and further in view of Haddrick *et al.* (J. Virol. Methods 61:89-93, hereinafter “Haddrick”). *See* Office Action at pages 12-13, § 26. Applicants respectfully traverse the rejections.

However, solely to advance prosecution, the presently pending claims have been amended to recite that the claimed composition is suitable to elicit production of an antibody which binds to the fusion-active form of an HIV gp41/gp120 complex, and thereby inhibits the fusion of gp41/gp120 with the membrane of a target cell. This element is not disclosed or suggested by any of the cited references, alone or in combination. As the cited references do not disclose all elements of the presently pending claims, these claims cannot be rendered obvious by the references. Applicants therefore respectfully request the reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance, or in better condition for appeal. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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